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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,486	11/13/2003	David A. Schechter	2876	8330

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EXAMINER	
PEFFLEY, MICHAEL F	

ART UNIT	PAPER NUMBER
3739	

NOTIFICATION DATE	DELIVERY MODE
12/28/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/712,486	SCHECHTER ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 26-28* is/are pending in the application.

4a) Of the above claim(s) *6 and 9-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8,21-23 and 26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/13/06* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 2, 2009 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7, 8, 21, 23 and 26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the originally filed specification for an elastomeric material that completely surrounds the electrode (claims 1, 21 and 23), or for the delivery of energy in a unidirectional manner (claim 22) as now set forth in the claims.

Regarding the elastomeric material, paragraph [0040] of the printed publication states that the elastomeric "substantially surrounds" the electrode. There is no description of an elastomeric matieral that "completely surrounds" the electrode. Moreover, the Figures show an elastomeric material that surrounds the electrode on three sides leaving the surface of the electrode uncovered (applicant's Figure 3, for example). Thus, the electrode is not "completely surrounded" as now set forth.

Regarding the limitation of energy flowing in a unidirectional manner, there is no such disclosure in the specification. It is noted that in a bipolar system, energy would generally flow from the active to the return electrode. However, stray currents are normally present, particularly if there is a fluid environment. There is nothing in applicant's original specification that describes the flowing of energy in a unidirectional manner.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the electrodes completely surrounded by the elastomeric material must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

Claims 1-3, 8, 21-23 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Truckai et al (6,770,072) in view of the teaching of Yates et al (5,810,811).

Truckai et al disclose a tissue or vessel sealing instrument comprising a housing (not shown) having a shaft (102 - Figure 1) attached thereto and defining a longitudinal axis (107). An end effector assembly is attached to the distal end of the shaft and includes first (105a) and second (105B) jaw members attached to the shaft and made from a substantially rigid material. The embodiment of Figures 19A and 19B shows a jaw formation (only the bottom jaw is shown) that includes a rigid material (705A) forming the jaw, and an elastomeric material (726) disposed on the inner surface of the jaw member for contact with tissue. Associated with the elastomeric material, and imbedded therein, are electrodes (730) having a planar tissue contact surface disposed

transverse to the longitudinal axis (735) of the jaw. Truckai et al show the same relationship between the elastomeric material and the electrodes. That is, the elastomeric material of Truckai et al surrounds the electrodes on three sides leaving the surface exposed exactly as is shown in applicant's figures. As such, the Truckai device is deemed to meet the newly added limitation of an electrode that is "completely surrounded" as best understood by applicant's figures. The elastomeric material is a silicone polymer (col. 16, lines 45-54) as disclosed and claimed by applicant, and would inherently, or at least obviously, have the same properties of compression. Truckai et al also teach that the upper jaw would have the same or similar construction (col. 16, lines 45-48). The only feature not expressly disclosed by Truckai et al is the offsetting of the electrodes when the jaws are closed on tissue.

Yates et al disclose another tissue grasping and sealing device and provide a variety of different electrode configurations for treating tissue. In particular, Figures 17 and 18 show an embodiment where it is preferable to provide the electrode members offset along the length of the jaw members to provide a current flow that is coplanar with the jaw contacting surfaces.

To have provided the Truckai et al sealing device with electrodes offset laterally and/or lengthwise along the length of the jaw member to provide an energy that flows coplanar with the tissue contacting surface would have been an obvious design modification for one of ordinary skill in the art since Yates et al fairly teaches it is known to provide such an arrangement of electrodes on an analogous sealing device.

Regarding claim 2, Truckai et al fully disclose the use of silicone and silicone polymers as asserted above, and the use of any other reasonable substitute is deemed an obvious design consideration.

Regarding claim 3, the particular offset distance is also deemed to be an obvious design consideration. Yates et al fail to disclose the specific offset distances, but the examiner maintains that one of ordinary skill in the art would be fully capable, without undue experimentation, of determining optimal spacings for a desired effect. Moreover, applicant's specification is void of any criticality of unexpected result associated with the particular spacing.

Regarding claim 8, the use of similar materials in Truckai et al are deemed to provide a comparable CTI as that set forth in this claim. Moreover, the specific material used and the CTI achieved is deemed a matter of obvious design choice, particularly since applicant's specification again fails to provide any criticality or unexpected result associated with this parameter.

Regarding claims 21 and 23, see rejection of claim 1 above. Further, Figures 19A and 19B clearly show the elastomeric material encompassing the electrode leaving only an exposed electrode surface flush with the elastomeric material (exactly as shown in applicant's figures). In view of the same structural relationship between the elastomeric material and the electrode, the Truckai material is deemed to meet the limitation of "completely surrounding" the electrode.

Regarding claim 22, the examiner again maintains that the Truckai device, as modified by the teaching of Yates et al, provides an electrode arrangement that is the

same as claimed and shown by applicant. As such, the electrical energy would inherently travel in a unidirectional manner between the active and return electrodes just as applicant's claimed device.

Regarding claims 26 and 27, again see the rejection of claim 1. The examiner maintains that the provided offset electrodes are inherently configured to result in a uniform temperature distribution. It is further noted that the Truckai et al disclose is particularly directed towards providing a uniform temperature along the jaw surfaces.

Claims 1-5, 7, 8, 21-23 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yates et al ('811) in view of the teaching of Phan (6,932,816).

Yates et al disclose a device for sealing vessels comprising a housing (16) having a shaft (30) attached thereto and defining a longitudinal axis. An end effector comprising first (32) and second) (34) jaws is attached to the distal end of the shaft and the jaws are movable relative to each other. Each jaw member includes electrodes having planar contact surfaces that are offset with respect to each other transverse to the longitudinal axis of the shaft (see Figures 17 and 18). The feature not expressly taught by Yates et al is the provision of an elastomeric material surrounding the electrodes.

Phan discloses another device having jaw members for grasping tissue. In particular, Phan teach that it is advantageous to provide the jaw member with an elastomeric material (106) made from silicone or silicone polymers (col. 6, lines 32-35). The material of Phan is deemed to inherently, or at least obviously, have the same

compression properties as applicant's elastomeric material since it is made from similar materials. Moreover, applicant's specification fails to provide any criticality or unexpected result for the particular compression characteristics.

Regarding the limitation that the electrodes are "completely surrounded", the examiner maintains that there is no clear support for such a limitation beyond what is shown in Yates et al. That is, applicant's drawings show an elastomeric material that surrounds the bottom and the sides of the electrode leaving the surface uncovered so as to treat tissue. This is identical to the Yates et al electrodes of Figures 17 and 18, except for the use of an elastomeric material as the support. As such, the combination of the Phan teaching, which provides motivation to surround the electrode with an electromeric material, with the Yates et al device, which provides electrodes completely surrounded except for the exposed surface, is deemed to read on the claimed limitations.

To have provided the Yates et al jaws with an elastomeric material surrounding the electrodes to provide a more flexible contact surface for the jaw members would have been an obvious modification for one of ordinary skill in the art since Phan teaches of the advantages of an electrode embedded in such an elastomeric material for the same purpose in an analogous tissue sealing device.

Regarding claim 2, Phan disclose the use of similar materials, and the use of any other reasonable substitute is deemed an obvious design consideration.

Regarding claim 3, the particular offset distance is also deemed to be an obvious design consideration. Yates et al fail to disclose the specific offset distances, but the

examiner maintains that one of ordinary skill in the art would be fully capable, without undue experimentation, of determining optimal spacings for a desired effect. Moreover, applicant's specification is void of any criticality of unexpected result associated with the particular spacing.

Regarding claims 4, 5 and 7, Phan et al fairly disclose the use of temperature sensors (146) for providing feedback information to control energy delivery (col. 10, line 54 to col. 11, line 20). Phan also discloses the means for selecting a desired electrode for activation based on sensed impedance or temperature (col. 11, lines 21-49).

Regarding claim 8, the use of similar materials in Phan is deemed to provide a comparable CTI as that set forth in this claim. Moreover, the specific material used and the CTI achieved is deemed a matter of obvious design choice, particularly since applicant's specification again fails to provide any criticality or unexpected result associated with this parameter.

Regarding claims 21 and 23, see rejection of claim 1 above. Further, Figure 8 of Phan clearly shows the elastomeric material encompassing the electrode leaving only an exposed electrode surface for contact with tissue. One of ordinary skill in the art would obviously be capable of using a similar arrangement surrounding the planar electrodes of Yates et al.

Regarding claims 22, 26 and 27, again see the rejection of claim 1. The examiner maintains that the provided offset electrodes are inherently configured to result in a uniform temperature distribution. It is further noted that the Phan fairly teaches providing one or more temperature sensors on the jaw members for

maintaining a desired temperature distribution along the jaw members. The electrode configuration is deemed to be inherently capable of providing unidirectional energy delivery given the similarity of the electrode relationship to applicant's electrodes.

Response to Arguments

Applicant's arguments filed December 2, 2009 have been fully considered but they are not persuasive.

Applicant continues to assert that the electrodes on each jaw of the Yates et al device are not offset with each other relative to the longitudinal axis of the probe. In particular, applicant points out an apparent discrepancy between Figures 17 and 18. Figure 17 shows the electrodes spaced longitudinally along the length with the same poles on one side of the device, while Figure 18 shows the electrodes having the same poles on one jaw and the opposite poles on the other jaw. The examiner maintains that the particular alignment for the poles, either all on one side of the device or one pole on one jaw and the other pole on the other jaw, is an obvious design expedient. Yates et al is merely showing that the staggered nature of the jaws is the desired design. Yates et al clarify in column 10, lines 41-51 that Figures 17 and 18 provide slightly different configurations that yield electrodes that are electrically isolated. Figure 13, similarly, shows yet another staggered configuration for the electrodes. The examiner maintains that such an isolation is the same general design concept of applicant's electrode poles as shown in the Figures. Applicant's specification fails to disclose any criticality or unexpected result associated with the specific electrode configuration, and . The examiner maintains that one of ordinary skill in the art would readily recognize the

effective current path provided by any arrangement of the electrodes, and that Yates et al clearly show that various types of configurations are contemplated to create an isolated current path between the electrodes.

Regarding applicant's arguments beginning on page 14 of the response, the examiner maintains that Yates et al clearly show electrodes that are "completely surrounded" by the support structure - at least to the same extent that applicant's electrodes are completely surrounded. While Yates et al do not surround the electrodes with an elastomeric material, the Phan teaching (as well as the Truckai teaching) is to show that it is known to provide electrodes surrounded by an elastomeric material provided on a support member, and that to have provided the Yates et al device with such an elastomeric support would be obvious in view of this teaching. Regarding the arguments on page 15 of the response, the examiner maintains that there would be energy between electrodes that flows transversely to a longitudinal axis of the jaw member. While Figure 18 shows an active electrode on top, and a return electrode aligned below, some current would also cross over to the return electrode on the other side of the jaw (which is similarly spaced from the active electrode given the staggered nature). Moreover, the embodiment of Figure 17 shows all active electrodes on one side of the device meaning the other side of the device would have the return electrodes and energy would necessarily flow transverse to the longitudinal axis of the jaw member.

The examiner continues to assert, as addressed in the earlier 35 USC 112, first paragraph rejection, that there is no support in applicant's specification for the

"unidirectional" flow of energy. Moreover, the Yates et al reference discloses various different types of electrode arrangements, including electrodes on opposite jaws and electrodes offset, that the energy flow would necessarily be similar to applicant's energy flow pattern.

On page 16 of the response, applicant contends that since Truckai disclose providing an exposed electrode surface flush with the elastomeric material, Truckai cannot teach of disclose an electrode that is completely surrounded by the elastomeric material. As addressed previously, Truckai's structure is identical to that shown in applicant's figures. Applicant fails to show, and fails to disclose, and electrode that is "completely surrounded". As such, this limitation is deemed new matter. In as much as the Truckai electrodes are provided with an identical structure to that shown in the applicant's figures (i.e. surrounded on three sides), this structure is deemed to meet the claimed limitations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
December 21, 2009